

REMARKS

I. Status of the Claims

Claims 1-18 are pending in the application. In response to the restriction requirement, applicant elected, with traverse, to prosecute claim 18, the Group II claim. Thus, claims 1-17 are withdrawn, and claim 18 is under consideration and stand rejected under 35 U.S.C. §112, first paragraph and 35 U.S.C. §103. The specific grounds for rejection, and applicant's response thereto, are set out in detail below.

II. Rejection under 35 U.S.C. §112

Claim 18 remains rejected as allegedly lacking enablement. The new basis for rejection is that, while the specification supports reduction of ethanol and acetaldehyde reduction in blood, the recited mechanisms for modulating ethanol metabolism are not proven. Once again, the rejection is traversed, but in the interest of advancing the prosecution, the claim has been amended to recite only the outcome which the examiner acknowledges is supported, while the mechanistic aspects have been removed. It is believed that the amendment overcomes the rejection, the reconsideration and withdrawal of which is hereby requested.

IV. Rejection under 35 U.S.C. §103

Claim 18 is rejected by the examiner under 35 U.S.C. 103(a) as being unpatentable over Popp *et al.* (U.S. Patent 6,630,158) and Amselem (U.S. Patent 5,989,583). Once again, applicants traverse.

The subject matter of claim 18 involves a **method** of affecting the alcohol metabolism by administering to a subject the recited food composition or dietary supplementation (*i.e.*, one

containing dextrose, Vitamin C, L-glutamine, cysteine, riboflavin, succinic acid and/or fumaric acid and coenzyme Q10), and wherein the method reduces ethanol and acetaldehyde in blood.

In response, the examiner cites to Popp *et al.*, which does **not** teach methods of affecting alcohol metabolism. At **best**, the reference provides a composition that does not include L-glutamine, cysteine or coenzyme Q10, much less the succinic acid and/or fumaric acid that the examiner admits are lacking. The only mention of L-glutamine, cysteine or coenzyme Q10 is in the background with reference to the prior art. The examiner appears to have completely ignored this point in the previously submitted response, and applicants request that the failure of Popp *et al.* to disclose L-glutamine, cysteine or coenzyme Q10 **in the compositions of the reference** be addressed on the record. The complete and utter inadequacy of Popp is further highlighted by the examiner's citation to column 3, lines 1-25 of the reference, which are nothing more than a list of U.S. RDA's for essential macro- and micronutrients. To rely on this passage as support for this rejection is simply untenable. Similarly, column 3, lines 46-67 of the reference describe *earlier* patents and the reference in no way incorporates their teachings for **in the compositions provided therein**. Finally, column 7, lines 61-67 are nothing more than a discussion of solid dosages forms.

Moreover, Popp *et al.* discloses methods of promoting and maintaining healthy skin using a composition containing essential ingredients lycopene carotenoids, biotin, chromium and selenium (see Popp *et al.*, column 4, l. 6-9). There is absolutely nothing in this reference regarding modulating alcohol metabolism. Amselem cannot correct this problem either as it too lacks any discussion of alcohol or alcohol metabolism. Thus, the examiner is left simply citing to elements of compositions in the two references. As a matter of law, citing compositions alone

against claimed **methods** is completely improper. In other words, the examiner is wrongly building a rejection against a claim that is not now pending.¹

The examiner's response to applicants' argument regarding the absence of alcohol metabolism disclosure in **either** reference is to argue that the effects would be "inherent to the method of the combined art." This argument is completely devoid of legal validity. There is simply no premise for the argument that, in the context of obviousness, two patents dealing with completely different purpose can be combined to render a third purpose "inherent." It is black letter law that "inherency" requires a **certainty** that the claimed invention has been made or practiced before. By definition, an obviousness scenario fails this standard. "Obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." MPEP §2141.02, citing *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). Here, the examiner has not even attempted to "establish" that the compositions of either Popp *et al.* or Amselem have the "certain feature" of modulating alcohol metabolism.

Even assuming that the foregoing deficiencies were somehow overcome (certainly not using only the references of record), the examiner's combination of Popp *et al.* with Amselem still is not well-founded. As mentioned above, the composition disclosed in Popp *et al.* is for promoting and maintaining healthy skin. Contrarily, Amselem discloses dry solid lipid compositions for the oral delivery of lipophilic substances, and methods for preparing and using such compositions. The lipid composition disclosed in Amselem showed higher bioavailability of lipophilic substances, such as coenzyme Q10 by addition of antioxidants, such as α -

¹ Indeed, the examiner argues that "one may choose to prepare a composition comprising all of the components taught by Popp" Action at pages 9-10. This passage further highlights that the fact that the examiner is simply citing compositions to obviate methods.

tocopherol (e.g., tocopherol succinate) which lessen the formation of oxidative degradation products from ***unsaturated lipids*** (Amselem, col. 6, l. 62 to col. 7, l.1-2).

From this, the examiner posits the combination of Popp *et al.* with Amselem solely on the grounds that “since coenzyme Q10 is a lipophilic substance, one of ordinary skill in the art would have been motivated to formulate a composition comprising this component in the presence of a lipid, and therefore would have been motivated to combine the components as taught by Amselem to prevent the formation of oxidative degradation products.” Action at pages 10-11. However, this statement is completely off the mark for the simple reason that ***Popp et al. does not teach compositions containing coenzyme Q10!!!*** There are only two references in the entire Popp *et al.* patent to coenzyme Q10, and they both cite to the prior art. Rather, Popp *et al.* characterize their invention as “a dietary composition for promoting and maintaining healthy skin containing essential ingredients lycopene carotenoids, biotin, chromium and selenium.” There is nothing about coenzyme Q10 here, nor is there in the balance of the Description of the Preferred Embodiments. As such, there is simply no reasonable argument that coenzyme Q10 was intended to be part of the Popp *et al.* compositions, and thus there is no rationale whatsoever to combine Popp *et al.* with Amselem.

Moreover, Amselem *et al.* fails to disclose succinic acid, but rather, provides α -tocopherol and its derivatives, including a succinate thereof. However, α -tocopherol succinate is ***not*** succinic acid, and for this reason alone one would not be instructed by Amselem to use succinic acid, but rather α -tocopherol succinate. The examiner argues that succinic acid would result from the dissolution of α -tocopherol succinate. However, while possibly relevant to a question of anticipation, here the issue is one of obviousness and what would be suggested to those of skill in the art. The claim requires administering succinic acid to a subject, and that is

not what Amselem teaches – it teaches administering α -tocopherol or α -tocopherol succinate. Thus, the skilled person would derive no suggestion from Amselem regarding succinic acid, further detracting from the viability of the rejection. This is yet another argument the examiner has completely and improperly ignored, and applicants request that it be addressed on the record.

Once again, applicants submit that the methods of the present invention are not obvious in view of Popp *et al.* and Amselem for at least the reasons that (a) the references fail to teach each element of the claimed invention, and (b) the combination of references is improper as neither reference nor the general knowledge in the field would provide the necessary motivation. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

V. Conclusion

In light of the foregoing, applicant respectfully submits that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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